IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	**MDL No. 1871** **07-md-01871**
THIS DOCUMENT APPLIES TO: ALL ACTIONS	:	

MEMORANDUM OPINION AND PRETRIAL ORDER NO. 84

RUFE, J. **December 7, 2009**

The Defendant, SmithKline Beecham Corporation d/b/a GlaxoSmithKline (GSK), has filed a Motion Appealing the Eighth Report and Recommendation of the Special Master as to Documents Withheld Pursuant to the Attorney-Client Privilege and/or the Work Product Doctrine ("R & R # 8").[1] After considering Defendant's Motion to Appeal, Plaintiffs' Response in Opposition, Defendant's Reply, and Plaintiffs' Sur-reply, and pursuant to this Court's power pursuant to 28 U.S.C. § 636(b)(1)(C) to make a *de novo* determination of proposed recommendations to which objections are made, the Court approves and adopts the recommendations contained in R & R #8 for the reasons set forth below.

PROCEDURAL HISTORY

The Special Master and the parties to this case have spent much of the past year trying to resolve a discovery dispute over Defendant's assertion of attorney-client privilege or work-product protection for tens of thousands of documents. Defendant submitted approximately 120 documents

[1] Doc. No. 525

to the Special Master for *in camera* review. Defendant objected to the Special Master's rulings on many of these documents, and also objected to his proposed comprehensive guidelines for applying attorney-client privilege or work product protection that the Special Master set forth in his Seventh Report and Recommendation to the Court. The Court did not adopt the recommended comprehensive guidelines, as the Court found them inapt for the litigation, and directed the parties to meet with the Special Master again to try to resolve the dispute. As a result of the Special Master's meetings and discussions with the parties, the number of documents for which privilege is claimed has been reduced from 120 to 25. The Special Master rejected Defendant's claim of attorney-client privilege and/or work-product protection as to each of these documents in R & R #8. The documents for which privilege and/or protection is claimed have also been submitted to this Court for *in camera* review, and the Court has reviewed each individual document carefully to determine whether privilege or work-product doctrine applies.

DISCUSSION

Attorney-Client Privilege

The attorney-client privilege exists to foster disclosure and communication between the attorney and the client. Nevertheless, because the privilege obstructs the search for the truth and because its benefits are, at best, "indirect and speculative," it must be strictly confined within the narrowest possible limits consistent with the logic of its principle.[2]

Pennsylvania law controls the privilege issues in this case. The Pennsylvania rule

[2] In re Grand Jury Investigation, 599 F.2d 1224, 1235 (3d Cir.1979)(internal citation omitted).

regarding confidentiality is codified at Pa. Const. Stat. Ann. §5928, which states:

> In a civil matter counsel shall not be competent or permitted to testify to confidential communications made to him by his client, nor shall the client be compelled to disclose the same, unless in either case this privilege is waived upon the trial of the client.

Determining whether this rule applies can be complicated in the corporate setting, where in-house counsel serve as both business advisors and legal advisors to corporations. In such situations, the federal courts have interpreted Pennsylvania law to require the party asserting the privilege to demonstrate that the *primary purpose* of the communication was to gain or provide legal assistance.[3]

> The privilege applies only if. . .[the communication was made] for the purpose of securing primarily either (i) an opinion on law or (ii) legal services or (iii) assistance in some legal proceeding.[4]

Defendant contends that the *primary purpose* requirement refers to the primary reason the document is sent to the attorney, not to the primary purpose of the document itself. This Court finds no support for such an interpretation in the cases applying Pennsylvania law, including in the Ford case cited by Defendant in support of its position, and finds such an interpretation inconsistent with the requirement that privileges must be narrowly construed. Nevertheless, the Court's analysis of the documents at issue in this case does not rest on the construction of the term "primary purpose."

Drafts of documents circulated to counsel for comments on legal issues may be

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[3] Southeastern Pennsylvania Transp. Authority v. Caremark PCS Health, L.P., 254 F.R.D. 253, 258 (E.D.Pa. 2008). See also, Ford Motor Co. v. Kelly, 110 F.3d 954, 965 (3d Cir 1997).

[4] In re Grand Jury Investigation, 599 F.2d 1224, 1233 (3rd Cir 1979), quoting United States v. United Shoe Mach. Corp., 89 F.Supp. 357, 358-359 (D.Mass. 1950). See also, Rhone-Poulenc Rorer v. Home Indemnity Co., 32 F.3d 851 (3d Cir. 1994)(using the same quoted language).

considered privileged if they were prepared or circulated for the purpose of obtaining a legal opinion and they contain *confidential information* or *legal advice* not included in the final version.[5] Even in these cases, the Court may find that only the portions of the draft reflecting the legal advice are privileged. However, if the attorney is primarily evaluating the *business* ramifications of a document or other communication, it will not be privileged.[6] "Courts have remained firm in denying privileged status to documents that contain essentially technical or business data and are not primarily legal in nature."[7] The party claiming the privilege must clearly show that a document is legal in nature or that it renders legal advice.

The attorney-client privilege does not shield documents merely because they were transferred or routed through an attorney. Otherwise non-privileged communications between corporate employees do not attain privileged status when counsel is copied on the correspondence.[8] Therefore, the corporation asserting the privilege must demonstrate that the communication was made for the *express purpose* of securing legal and not business advice.[9]

Work-Product Doctrine

Federal Rule of Civil Procedure 26(b)(3) governs attorney work product doctrine. Generally, a party may not discover documents that are prepared in anticipation of litigation, unless they are otherwise discoverable and the requesting party demonstrates a substantial need for the

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[5] Allegheny Ludlum Corp. v. Nippon Steel Corp., 1991 WL 61144 at *5 (E.D.Pa. April 15, 1991).

[6] Allegheny Ludlum Corp., 1991 WL 61144 at *2.

[7] Allegheny Ludlum Corp., 1991 WL 61144 at *3.

[8] Southeastern Pa. Transp. Auth., 254 F.R.D. at 259.

[9] AAMCO Transmissions, Inc. v. Marino,1991 WL 193502, *3 (E.D.Pa. Sept. 24,1991).

materials to prepare its case and cannot obtain the equivalent information by other means.[10] Even when work product documents are discoverable, "mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the litigation" are protected against disclosure.[11]

The Third Circuit has held that only documents that were prepared or obtained *because of* the pending or threatened litigation are protected from disclosure.[12] That is, the "primary motivating purpose behind the creation of the document [must be] to aid in possible future litigation."[13] Work product prepared in the ordinary course of business is not immune from discovery.[14] For example, documents prepared by a corporation as part of efforts to ensure compliance with federal regulatory agencies or maintain a positive public image for its products, and not because of possible litigation, are not protected by work-product doctrine.[15]

The party asserting the work-product privilege has the burden of proving that the protection is applicable.[16]

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[10] Fed. R. Civ. P. 26(b)(3)(A).

[11] Fed. R. Civ. P. 26(b)(3)(B).

[12] Martin v. Bally's Park Place Hotel & Casino, 983 F.2d 1252, 1260-61 (3d Cir. 1993).

[13] United States v. Rockwell Int'l, 897 F.2d 1255, 1266 (3rd Cir. 1990) (finding the "primary motivating purpose"standard adopted by the Fifth Circuit to be analogous to the Third Circuit's "because of" standard).

[14] Holmes v. Pension Plan of Bethlehem Steel Corp. 213 F.3d 124, 138 (3d Cir. 2000).

[15] In re Grand Jury Subpoena, 220 F.R.D. 130, 157 (D. Mass. 2004); Fed. R.Civ. P. 26(b)(3), adv. comm. note (1970).

[16] Holmes, 213 F.3d at 139.

Analysis of Documents

With these legal principles in mind, the Court will review the documents presented for *in camera* review.

Document #1 AVMDLZ00140748-00140781

Document #1 is a September 26, 2001 e-mail from attorney Robert McRae to Margaret Kreider, with a copy to another attorney (Kurt Henjes) and ten non-attorney employees, in which he writes only "looks good" (regarding the attached draft prescribing information for Avandamet). The GSK privilege log describes this document as "Regulatory documents containing legal advice from Rob MacRae, Esq. regarding communications with a government authority, and sent to Kurt Henjes, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

The Court finds that this e-mail message is not covered by attorney-client privilege. The e-mail from McRae does not provide any substantive advice which would be confidential. Therefore, while this comment does render legal advice, it is not protected (although the attachment it comments upon could be privileged). Although the e-mail is copied to another attorney, Henjes, it does not ask him to provide any legal advice, and therefore the Court cannot find that a primary purpose of the e-mail was to request legal advice, despite GSK's characterization in its privilege log.

An earlier e-mail in the chain, dated September 25, 2001, was sent by non-lawyer Margaret Kreider to various employees, including two attorneys, with the draft prescribing information. She asks for final comments or revisions on that document. The primary purpose of that e-mail is to solicit comments about the prescribing information. By sending the e-mail to two

attorneys, she may be seeking direction from the legal department about whether there are "adequate directions for use" and "adequate warnings,"[17] which is arguably legal and not technical advice. However, the e-mail message does not contain any confidential information. Therefore, this communication is not privileged.

Turning finally to the attachment, which contains the draft prescribing information, it appears that most of the information in this document was already published in prescribing information for other GSK drugs. Such information would not be confidential. However, even looking at the document as a whole, the Court finds that the Defendant has not proved that the attached draft prescribing information contains confidential information or legal advice not included in the final (non-confidential) version. Examining the edits made to the prescribing information document itself, some of which may have been made by legal counsel, although the Defendant does specifically so allege, the Court finds no confidential information or legal advice which is not found in the final version released to the public. Therefore, the attachment is also not privileged.

Work-product doctrine does not apply to the e-mail or the attachment because it was produced in compliance with federal regulations, and not because of pending or threatened litigation.

Document #1 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #2: AVMDLZ00094684, 94685, 94703

Document #2 is a July 26, 2007 e-mail from GSK employee Amy Ebel to Margaret Kreider, with copies to various other employees including one attorney. Attached are two documents

[17] MacKrae Affidavit ¶7.

with proposed prescribing information for Avandia. The e-mail refers to a meeting earlier that day at which the recipients of the e-mail agreed on "boxed warning" language. The e-mail directs their attention to the edits in the boxed warning, and asks for an e-mail formalizing the earlier approval. One attorney is among the recipients who are asked to provide formal approval of the attachment. Defendants characterize this document as "Regulatory documents sent to Stuart Greer, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

The Court finds that there is no confidential information in the e-mail which requests review and approval. Therefore, the e-mail is not subject to attorney-client privilege.

The boxed warning language in the attached document is nearly identical to the final boxed warning label approved by the FDA and distributed publically. The changes made were not substantive edits, and the draft boxed warning label contains no confidential information excluded from the final version.[18] Therefore, neither the e-mail not the attachment are privileged documents.

Work-product doctrine does not apply to the e-mail or the attachment because it was produced in compliance with federal regulations, and not because of pending or threatened litigation.

Document #2 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #3: AVMDLZ00061220-61225

This set of documents dated July 26, 2007 consists of four e-mails from recipients

[18] The Court assumes that the remainder of the prescribing information was unchanged from the non-confidential version previously provided to the public. Additionally, the Court finds no differences between the draft attached to Document 2 and the final published version of the prescribing information which contain confidential information or legal advice. See Final Versions Binder, Exhibit 3. GSK does not point out any substantial differences, confidential information or legal advice in support of its assertion of privilege.

of the e-mail discussed above (Document #2). The first, from Dr. Alexander Cobitz to Amy Ebel (both non-attorneys), says "AGREED." The second, from Willa Phyall to Amy Ebel (both non-attorneys) is specifically addressed to Amy and suggests striking the words "100 count bottle" for consistency with an Avandia prescribing information form previously submitted to the FDA. The third, from Lauren Karak to Amy Ebel (both non-attorneys) says "Amy, I am ok with this text, Best Regards, Lauren." The fourth, from Dr. Eric Dube to Amy Ebel (both non-attorneys) read "I approve." There were no attachments to these emails, but the earlier e-mail from Amy Ebel to Margaret Kreider, which was discussed above (Document #2) and determined to be non-privileged, was included in each of these messages. Copies of each of these messages were sent to other employees, including attorney Stuart Greer. The GSK privilege log characterizes these e-mail messages as "E-mail sent to Stuart Greer, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

Although attorney Stuart Greer is copied on each of these e-mail messages, none of the four e-mail messages request legal advice, nor do they contain legal advice or confidential information. This set of documents is not privileged.

Work-product doctrine does not apply to the e-mail or the attachment because it was produced in compliance with federal regulations, and not because of pending or threatened litigation.

Document #3 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #4: AVMDLZ00048693-48695

This document is an e-mail message dated August 22, 2007 from GSK employee

David Cocchetto to GSK employees Doctor Krall and Doctor Slaoui, with copies to other GSK employees. None of the recipients of the e-mail are attorneys. It discusses changes to prescribing information for Avandia, which were agreed upon in an early meeting. An attachment contains the draft labeling information, with the edits visible on the face of the document. It is not apparent who made the edits. An early e-mail in the chain was sent from employee Traci Lee to various GSK employees, one of whom is an attorney, asking for approval of proposed Avandia label information. That e-mail specifically requests approval from Stuart Greer, Esq. GSK's privilege log describes this e-mail as "E-mail communications sent to Stuart Greer, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority," and the attachment as "Regulatory documents sent to Stuart Greer, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

The primary e-mail clearly is not a request for legal advice, and it does not appear to contain any legal advice. While the earlier message in the chain did include a request for legal advice, that message did not contain any confidential information which would be protected by privilege.

The attached prescribing information document is a draft internal document which incorporates comments from GSK employees, including possibly attorneys. GSK has not provided any evidence to the court, through affidavits or otherwise, that the comments and edits to the document were made by attorneys, that they contain legal advice, or that they were made pursuant to legal advice. Additionally, the attachment does not appear to contain confidential information or

legal advice not found in the document provided to the FDA.[19] Therefore, although the attachment was circulated to many employees, including an attorney, for review and approval, the Court does not find that attorney-client privilege applies.

Work-product doctrine does not apply to the e-mail or the attachment because it was produced in compliance with federal regulations, and not because of pending or threatened litigation.

Document #4 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #5: AVMDLZ00176475

Document #5 is an e-mail message dated July 26, 2007 from Alexander Cobitz to Eric Dube (both non-attorney GSK employees). Copies of the message were sent to other employees, including one attorney, but the message itself is clearly addressed to "Eric" and not to a larger audience. The message essentially says that the draft professional fair balance documents for each of four products "look ok", but the box warning may need to be adjusted in the future. It was written in response to an earlier message from Eric Dube seeking the feedback of four GSK employees, including one attorney. The four attachments to the earlier e-mail in the chain were deleted from the reply. The GSK privilege log describes this as "e-mail sent to James Schell, Esq. for the purpose of obtaining legal advice regarding communication with a governmental authority."

The Court finds that Alexander Cobitz's response is not privileged, as it does not contain or request legal advice. The earlier e-mail in the chain, which is a request for feedback, does

[19] See Final Versions Binder, Exhibit 2(B). Again, GSK does not allege that the draft attachment contains any confidential information or legal advice not contained in the version provided to the FDA.

contain a request for legal advice (approval) from an attorney, but the request itself contains no confidential information. If it did contain confidential information, that information could be redacted and the reply from Alexander Cobitz would still be discoverable. The attachments, which might contain confidential information, are no longer a part of this document as they were deleted by those whose responded to the e-mail.

Work-product doctrine does not apply to the e-mail because it was produced in compliance with federal regulations, and not because of pending or threatened litigation.

Document #5 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #6: AVMDLZ00063423

Document #6 is an August 21, 2007 e-mail from David Cocchetto to Willa Phyall, both non-attorney GSK employees. It reads "Here is the revised draft labeling that should be submitted on August 24." An earlier e-mail in the chain was addressed to a group of GSK employees, including one attorney, and it includes a request for approval of draft proposed Avandia prescribing information. The attachment referred to in the earlier e-mail in the chain is not included in the exhibit. GSK's privilege log describes Document #6 as "E-mail communications sent to Stuart Greer, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

Neither the request for approval nor the later e-mail contain any confidential information. To the extent that the earlier e-mail, requesting approval from a lawyer among others, was privileged, it could be redacted and David Cocchetto's message would be discoverable. If the

attachment is still associated with David Cocchetto's e-mail message, it may be confidential if it contains confidential information or legal advice not included in the version of the prescribing information that was released to third parties.

Work-product doctrine does not apply to the e-mail or the attachment, if any, because it was produced in compliance with federal regulations, and not because of pending or threatened litigation.

Document #6 should be produced to the Plaintiffs' Steering Committee. It there is an attachment containing any confidential information or legal advice, that information may be redacted.

Document #7: AVMDL00176356 and AVMDL00176357

Document #7 is a July 25, 2007 e-mail from Carol Koro to Melinda Stubbee, both non-attorney GSK employees. A copy of this e-mail was sent to attorney James Schell, among others. There is no confidential information in this e-mail, and there is also no request for legal advice. An earlier e-mail in the chain was sent from Melinda Stubbee to Carol Koro, with copies to other employees, including attorney James Schell. It is not clear whether the e-mail is requesting review of the "epi Q & A" document or thanking the recipients for their prior review. Reading it as a request for review, this does appear to be a request for legal advice, as well as a request for technical advice from the non-lawyers. GSK's privilege log characterizes Document #7 as "e-mail sent to James Schell, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority," and the attachment as "media communications sent to James Schell, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

The e-mails contained in Document #7 are not subject to privilege. The primary e-mail from Carol Koro does not contain legal advice and does not request legal advice. The earlier e-mail in the chain from Melinda Stubbee does appear to request legal advice, but does not contain confidential information.

The referenced attachment, "epi Q & A,"was deleted from the e-mail sent by Carol Koro, the primary e-mail in Document #7. Therefore, although the attachment was submitted to the Court for *in camera* review, the Court does not believe that the attachment is discoverable as part of Document #7. However, the Court will review it for privilege in conjunction with the earlier e-mail, which asked James Schell, Esq., in addition to non-lawyer employees, to review the document before the information was released to the press or the public. Mr. Schell's affidavit asserts that the draft reflects "highly confidential advice provided by the GSK attorneys to their client representatives," but he points to no specific examples. Although edits and notes (including questions to be addressed) are apparent on the face of the July 25, 2007 version of the document, it is not clear which, if any, of these were made by attorneys. The comments and questions are primarily requests for technical clarification. The Court finds that regardless of who made these comments, they reflect technical advice and not legal advice. The one comment which arguably has legal implications (found in Question 16) actually outlines a problem and then poses a question ("suggested response?")– it does not provide any legal advice or propose a course of action.[20] In addition, the Court finds no confidential information or legal advice in this version which is not

[20] In any case, as noted above, the Court cannot ascertain whether this comment was made by an attorney or another reviewer.

found in the final version of the document created the same day.[21] Therefore, the Court does not find that this document meets the standard for privilege set forth in Allegheny Ludlum Corp.[22] It should be produced to Plaintiffs' Steering Committee.

Work-product doctrine does not apply to the e-mail or the attachment because it was produced for media presentations, with the goal of maintaining a positive public image for its product, and not to aid in pending or threatened litigation.

Document #7 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #8: AVMDLZ00095048

Document #8 is a July 30, 2007 e-mail from Hubert Chou to Amy Ebel, both non-attorney GSK employees. Copies of the e-mail were sent to twelve other GSK employees, including one attorney (Stuart Greer). The e-mail reads "I am fine with the wording. Thanks." An earlier e-mail in the chain is from Amy Ebel to Hubert Chou and other GSK employees, including Stuart Greer. It thanks them for their contributions, provides drafts which incorporate their comments on proposed labeling information regarding fractures, and asks the recipients to sign off on those drafts, as Chou did by his e-mail. The attachment on which they commented was deleted by Chou in his e-mail to Ebel. GSK's privilege log describes Document #8 as "E-mail sent to Stuart Greer, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

The e-mail from Chou to Ebel is clearly not privileged, as it does not ask for or

[21] Final Versions Binder, Exhibit 13

[22] Supra.

provide legal advice. The earlier e-mail in the chain does include a request for approval of draft prescribing information from an attorney, as well as from the non-attorneys. However, it does not contain any confidential information. Therefore, attorney-client privilege does not apply. If the message did contain confidential information, the proper course of action would be to redact the earlier e-mail message or the confidential information. The message from Chou to Ebel would not be protected.

Work-product doctrine does not apply to the e-mail because it was produced in response to federal regulations, and not because of pending or threatened litigation.

Document #8 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #9: AVMDLZ00063379 and AVMDLZ00063383

Document #9 consists of an e-mail message dated August 21, 2007 and an attachment. The attachment is a draft slide presentation containing information to present in response to physician questions about Avandia. The primary e-mail was sent from Alan Metz to Pearl Pugh (both GSK non-attorney employees). Copies were sent to ten other GSK employees including two attorneys, and the e-mail appears to address the group as a whole. The GSK privilege log characterizes the documents as "E-mail sent to Stuart Greer, Esq. and James Schell, Esq. for the purpose of obtaining legal advice regarding communications with medical professionals" and "Memorandum sent to Stuart Greer, Esq. and James Schell, Esq. for the purpose of obtaining legal advice regarding communications with medical professionals."

The e-mail message from Alan Metz sets forth his comments on the presentation. As

he is not a lawyer, his comments are technical and not legal. The e-mail does not request legal advice from any of the recipients. It does suggest soliciting clarification from "Carol," a recipient of the e-mail who is not a lawyer, in accord with suggestions made by "David C.," a recipient of the e-mail who is not a lawyer. Assuming that the "Jim" referred to in the last paragraph of the e-mail is James Schell, Esq., it appears that the concerns he raised were technical and not legal, as the same concerns were raised by other employees who are not lawyers. In any case, that section could be redacted if the concerns he raised were legal in nature.

Earlier e-mails in the chain do request feedback from the recipients, including lawyers, but these do not contain any confidential information. Therefore, they are not privileged.

The attachment to this e-mail does not reflect any confidential information or legal advice not found in the final version reviewed by the court.[23] Although there are differences between the two documents, they are in the nature of edits for clarity, not substance, and the Court finds no evidence of modifications made in response to legal advice. Therefore the draft document is not covered by attorney-client privilege.

Work-product doctrine does not apply to the e-mail or the attachment because it was produced with the goal of maintaining a positive public image for its product, especially among prescribing physicians, and not to aid in pending or threatened litigation.

Document #9 should be produced to the Plaintiffs' Steering Committee with confidential or legal advice (but not technical advice) provided by James Schell, Esq., if any, redacted.

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[23] Final Versions Binder, Doc. 9.

Document #10: AVMDLZ00060996

Document #10 is an e-mail message dated July 24, 2007 from David Cocchetto to Eric Dube. Neither is an attorney. Although others are copied on the message, including attorney James Schell, the main purpose of the e-mail is to provide Eric Dube with logistical information about upcoming review and copy-approval meetings. The end of the e-mail reads "I welcome further guidance from Paul and Jim." An earlier e-mail in the chain is a July 24, 2007 e-mail from Eric Dube to a "team" which includes an attorney. That message contains a request for review and approval of "key materials" which are not attached to the e-mail. GSK's privilege log describes Document #10 as "E-mail sent to James Schell, Esq. for the purpose of obtaining legal advice regarding Avandia resource materials."

While the Court finds that the primary e-mail does contain a request for legal advice, the Court finds no confidential information contained in that request. Therefore, the primary e-mail is not privileged. However, the Court finds that the earlier e-mail in the chain, from Eric Dube to "Team" contains a request for legal advice and confidential information. Therefore, the earlier e-mail in the chain may be redacted as privileged when the primary e-mail message is produced.

Work-product doctrine does not apply to the primary e-mail because it was produced for sales representatives to use, with the goal of maintaining a positive public image for its product, and not to aid in pending or threatened litigation.

The primary e-mail in Document #10 should be produced to the Plaintiffs' Steering Committee with the earlier e-mail in the chain (from Eric Dube) redacted.

Document #11: AVMDLZ00176448

Document # 11 consists of an e-mail message dated July 26, 2007 from Melinda Stubbee to Margaret Kreider (both non-attorneys) and two attachments dated July 25, 2007. The attachments are a draft Q&A for use with the media and a draft press release. Attorney James Schell reviewed and added his comments to both draft documents. GSK's privilege log describes the attachments as "Memorandum containing legal advice from James Schell, Esq. regarding media communications."

The e-mail message itself does not request or contain legal advice and it is not addressed to an attorney. Therefore, it is not privileged. As for the attachments, the Court agrees with the Special Master that GSK should redact the attorney comments on the attachments and then produce the redacted documents. Upon review of the final versions of these two documents[24] the Court finds that no confidential information about the legal advice provided would be revealed by a comparison of the redacted draft document and the final version.

Work-product doctrine does not apply to the attachments because they were produced for release to or discussions with the media, with the goal of maintaining a positive public image for the product, and not to aid in pending or threatened litigation.

Document #11 should be produced to the Plaintiffs' Steering Committee with counsel's comments on the attachment redacted.

[24] Final Versions binder, Docs. 11 and 12.

Document #12-15: AVMDLZ00103119, AVMDLZ00103132, AVMDLZ00103066 and AVMDLZ00102659

Document #12 is a July 23, 2007 draft of GSK's reactive statement for use in responding to media inquiries about the Actos meta-analysis. Document #13 is a July 22, 2007 draft of the same statement. Document #14 is a July 23, 2007 list of key messages, proof points and a Q &A regarding Avandia and cardio-vascular risk. Document #15 is a June 22, 2007 list of key messages titled Avandia vs. Actos. All four documents are clearly marked "Confidential," "Attorney Client Privilege" and "Confidential Attorney Work Product." GSK's privilege log describes Document #12 as "Media communications created for the purpose of obtaining legal advice regarding Avandia studies." The GSK privilege log describes Documents #13-15 as "Memorandum created for the purpose of obtaining legal advice regarding media communications."

While the Court credits GSK's assertion that GSK sought review and approval from its attorneys regarding some version of these documents before they were finalized,[25] the Court finds that the company's primary purpose in creating these draft public statements was not to obtain legal advice or to defend against lawsuits. The primary purpose of these draft public statements was to control the company's message to the media, critique a study that was harmful to GSK, and maintain a positive public image for their product. The draft documents before the Court do not appear to contain any legal advice or confidential information, and there is no accompanying request for legal review or comments on legal issues. GSK does not point to any particular confidential statements which appear in the draft versions but were removed from the final version based on legal advice. Therefore, the Court finds that the documents are not protected by attorney-client privilege. GSK

[25] See Greer Decl. ¶¶ 43-46; Schell Aff. ¶¶27-31; Christopher Aff. ¶¶23-26.

concedes that they are not protected by the work product doctrine.[26]

Documents #12-15 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #16: AVMDLZ00046916

Document #16 is an e-mail dated July 24, 2007 from Joanna Balcarek to nine GSK employees, including a copy to one GSK attorney, Bill Christopher. The e-mail simply reads "The working version of the presentation as it stands now." The presentation (draft slides) is attached. According to GSK, this slide show was prepared for a joint public meeting held by two FDA Advisory Committees to discuss the alleged cardiovascular risks of Avandia. GSK refers to this meeting as the "Ad Com." The agenda for the Ad Com was to vote on whether the risk-benefit profile of Avandia supported its continued availability in the United States, and to discuss how to minimize risks if it did remain on the market.[27] The GSK privilege log describes the document as "E-mail sent to William Christopher, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority," and the attachment as "Memorandum sent to William Christopher, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

The e-mail provides information to the recipients. It does not contain a request for legal advice, nor does it contain confidential information. Therefore, it is not protected by attorney-client privilege. Some version of the presentation was apparently reviewed by attorney William

[26] See GSK's Motion Appealing the Eight Report and Recommendation, FN 7.

[27] See GSK's Motion Appealing the Eight Report and Recommendation, p. 16.

Christopher before the final presentation. According to GSK, he reviewed the slide show because the presenters would likely be deposed about their statements to the FDA in pending litigation, and therefore they needed legal advice on the contents. The Court has compared the draft version attached to Document #16 to the final version presented to the FDA. While there are some minor differences between the early draft and the final presentation, the Court has been provided with no basis for concluding that the draft contains legal advice, that the changes were the result of legal advice, or that the information not included in the final version is confidential.

Document #16 should be produced to the Plaintiffs' Steering Committee. If there is confidential information or information which would reveal legal advice in the draft slide show, that information may be redacted.

Document #17: AVMDLZ001002676

Document #17 is a July 22, 2007 draft Q&A for an Ad Com meeting on Avandia. There is no message or request for review attached to this document, and therefore it is not clear who wrote it or to whom, if anyone, it was circulated for review. The GSK privilege log characterizes Document #17 as "Media communications created for the purpose of obtaining legal advice regarding communications with a governmental authority."

The Court agrees with the Special Master that GSK has failed to demonstrate that this constitutes a confidential communication made for the primary purpose of obtaining or providing legal advice. Moreover, GSK has failed to show that the draft contains confidential information or legal advice not found in the final version. Therefore, this draft document is not privileged.

Additionally, there is no evidence that Document #17 was produced because of the

prospect of litigation, rather than for business purposes and as a response to the request of a regulatory agency. Therefore, the document is not protected by the work-product doctrine.

Document #17 should be produced to the Plaintiffs' Steering Committee without redaction.

Documents #18-20: , AVMDLZ00047069, AVMDLZ00047073, AVMDLZ00047079

Documents #18-20 are e-mails regarding draft oral statements the GSK employees intended to present at the Ad Com. GSK's privilege log describes each of these documents as "E-mail sent to William Christopher, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

The earliest e-mail in the chain for each of these three documents is a "very rough" draft of the conclusion to Ronald Krall's Ad Com presentation, sent on July 24, 2007. The salutation specifically addresses three GSK employees, Moncef Slaoui, Patrick Vallance, and Lawson Macartney, none of which is an attorney. At the end of the e-mail, Mr. Krall specifically addresses "Moncef and Patrick" about his discomfort with this draft conclusion, as it may undermine the business goals of the company. A copy was sent to William Christopher, an attorney, but he was not specifically addressed or asked for input or review.

This e-mail from Ronald Krall does contain confidential information, as it discusses GSK's business goals and the possible business ramifications of the document in its present form, information that would not be presented to the public at the Ad Com. However, that information is not communicated to Mr. Krall's co-workers for the purpose of obtaining legal advice, and although it was copied to Mr. Christopher, nothing in the document suggests that it was circulated for the

purpose of obtaining legal advice from Mr. Christopher at that early point in the drafting process. Simply routing a document through an attorney is not sufficient to confer privileged status. The party claiming privilege must clearly show that a document is legal in nature or that it was sent for the express purpose of seeking or rendering legal (and not business) advice. Therefore, attorney-client privilege does not apply.

The primary e-mail in Document #18, dated July 25, 2007, is a message from Moncef Slaoui to Ronald Krall. Both are non-attorney GSK employees. The e-mail does not contain legal advice or request legal advice, nor does it contain confidential information. The earliest e-mail in this chain is discussed above. The chain also contains two other responses to the draft between non-attorney employees. These messages do not contain legal advice or request legal advice, although copies were sent to the attorney, nor do they contain confidential information. Therefore, Document #18 is not protected by attorney-client privilege.

Document #19 is another e-mail with proposed concluding statements for the Ad Com, this one from Moncef Slaoui sent on July 25, 2007. The salutation specifically addresses three GSK employees, Ronald Krall, Lawson Macartney, and Patrick Vallance, and a copy of the e-mail is sent to William Christopher, Esq. The e-mail does not contain legal advice nor does it include a request for legal advice. Furthermore, the Court has heard no evidence that this e-mail message contains information or legal advice not found in the public presentation at the Ad Com. Therefore, this e-mail message is not protected by attorney-client privilege. The earlier e-mail in the chain, from Ronald Krall, was discussed above.

Document #20 is a July 25, 2007 e-mail from GSK employee Lawson Macartney to

Ronald Krall. William Christopher, Moncef Slaoui and Patrick Vallance received copies. The salutation addresses only Ronald Krall, and is a response to Mr. Krall's draft presentation e-mail, which was discussed above. In this e-mail, Dr. Macartney expresses agreement with the concerns Mr. Krall raised in his earlier e-mail, about the business ramifications of presenting the data in a certain manner. Dr. Maccartney suggests a closing message to Mr. Krall. He closes the e-mail by stating that he will stop by Mr. Krall's office "in a few minutes to discuss." There is no indication that the issues raised are legal; they are clearly business concerns. Furthermore, there is no indication that the e-mail is seeking legal advice on which approach to take in the presentation. As with the earlier e-mail in the chain, the Court finds that attorney-client privilege does not apply.

Work-product doctrine does not apply to the documents because they were produced for presentation to a government agency in an effort to keep Avandia on the market, and not to aid in pending or threatened litigation.

Documents #18-20 should be produced to the Plaintiffs' Steering Committee without redaction.

Documents # 21 and 22: AVMDLZ00053497, AVMDLZ00053492

Document # 21 is an August 22, 2007 e-mail message from GSK employee Lucille Castagna to her co-workers, Laraine Caponi and Christina Mishinkash regarding a telephone conference with an FDA inspector. None of these employees are attorneys. The earlier e-mail in the chain is from Ed Pattishall to seven GSK employees, one of whom is an attorney, and it also discusses the FDA conference. In this e-mail, one employee, who is not an attorney, is asked to provide follow up information, and the information requested is not legal in nature. The GSK

privilege log describes this document, as well as Document #22, as "E-mail communications sent to William Zoffer, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

Document # 22 is a second August 22, 2007 e-mail message from GSK employee Lucille Castagna to her co-workers, Laraine Caponi and Christina Mishinkash regarding the telephone conference with an FDA inspector. It forwards an earlier e-mail from GSK employee Doug Butler to twelve GSK employees, one of whom, William Zoffer, is an attorney. That e-mail message establishes a "key team" to meet with the FDA inspector regarding Avandia. The team does not include any attorneys, and the e-mail does not invite the attorney to the advance meeting where the team will prepare for the meeting with the FDA inspector.

The primary e-mail messages in Documents #21 and 22 do not contain legal advice or request legal advice, and they are not sent to an attorney. As such, they are not privileged. GSK has not demonstrated that the earlier e-mail messages in the chains are privileged either. While an attorney did receive a copy of both earlier e-mail messages, neither addresses or seeks advice from the attorney. Furthermore, the messages do not contain confidential information. The e-mail messages outline issues the GSK employees should be prepared to cover, but as these issues were garnered from GSK employees' discussions with the FDA inspector, the information is not confidential.

The e-mail from Doug Butler reminds the recipients that the meeting with the FDA

inspector was a routine pharmacovigilance inspection,[28] not a "for cause" inspection.[29] Preparations made in anticipation of this regulatory inspection were not preparations made in anticipation of litigation. Therefore, the documents are not protected by the work-product doctrine.

Documents #21 and 22 should be produced to the Plaintiffs' Steering Committee without redaction.

Document #23: AVMDLZ00099847

Document #23 is a July 2007 draft "Dear Health Care Provider" letter regarding changes to the prescribing information for Avandia. Specifically, it addresses the new boxed warning regarding heart failure and contraindications for use. GSK asserts only attorney-client privilege for this document. GSK's privilege log describes Document #23 as "Letter created for the purpose of obtaining legal advice regarding communications with medical professionals." The draft document is labeled "Privileged and Confidential" and "Seeking legal advice."

The Court finds no confidential information or legal advice in the draft document which does not appear in the final, non-confidential version. Therefore, although the Court credits attorney Greer's affidavit regarding her role in drafting this document, attorney-client privilege does not apply.

Document #23 should be produced to the Plaintiffs' Steering Committee without redaction.

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[28] Attorney Zoffer's affidavit explains that the FDA performs routine inspections from time to time, to ensure that pharmaceutical companies are in compliance with FDA regulations. In August 2007, a routine inspection was scheduled. Due to concerns about the cardiovascular safety profile of Avandia, the FDA indicated that it would be focusing on Avandia during the inspection.

[29] See Document 22.

Document #24: AVMDLZ00178027

Document #24 is an August 20, 2007 e-mail message from GSK employee Paul Huckle to GSK employee Lucille Castagna, copied to twenty-six GSK employees, two of whom are attorneys, and to one outside counsel. The e-mail is a comment by Mr. Huckle, a non-attorney, regarding Section 5 of a draft submission to the FDA. It simply states his opinion that a small section of that document needs to be reworded for clarity, and quotes that section in full. GSK asserts the attorney-client privilege, describing the communication as "E-mail sent to Christina Diaz, Esq., Sean Fahey, Esq., and Stuart Greer, Esq. for the purpose of obtaining legal advice regarding communications with a governmental authority."

The e-mail does not contain any confidential information or legal advice not found in the final, non-confidential version of the document.[30] Therefore, even assuming that the feedback was sent to and reviewed by the attorney prior to publication,[31] this document is not protected by attorney-client privilege.

The e-mail was prepared not because of pending litigation, but rather as part of GSK's efforts to comply with a federal regulatory agency. Therefore, the e-mail is not protected by work-product doctrine.

Document #24 should be produced to the Plaintiffs' Steering Committee without redaction.

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[30] Final Versions binder, Doc. 7.

[31] Greer Decl. at ¶ 58.

Document #25: AVMDLZ00047453, AVMDLZ00047454, AVMDLZ00047496, AVMDLZ00047524

Document #25 is an e-mail message dated July 31, 2007 with three attachments. GSK employee Suzette Osei sent this message to eight GSK employees, one of whom is an attorney (William Christopher). The salutation is directed only to two employees, Ronald Krall and Trevor Gibbs, who are not attorneys. It asks only those two employees for "input and approval." The attachments are draft Global Data Sheets for Avandamet, Avandia, and Avandaryl. The GSK privilege log describes the e-mail as "E-mail sent to William Christopher, Esq. for the purpose of obtaining legal advice regarding Avandia resource materials" and the attachments as "Memorandum sent to William Christopher, Esq. for the purpose of obtaining legal advice regarding Avandia resource materials."

The e-mail contains no request for legal advice, and contains no confidential information or legal advice. Therefore, it is not privileged. The draft documents attached may be privileged if they were circulated for the purpose of obtaining a legal opinion *and* they contain confidential information or legal advice not included in the final version. The Court notes that the changes made between the drafts at issue and the final versions[32] relate to cardiovascular issues, and therefore these changes may have been made by lawyers or in response to legal advice. If the draft documents do contain confidential information and/or legal advice not found in the final versions, that information should be redacted and the remainder of the document should be produced.

Work-product doctrine does not apply to the e-mail or the attachments because they

[32] Final Version binder, doc. 5.

were produced in compliance with foreign regulatory requirements, and not because of pending or threatened litigation.

Document #25 should be produced to the Plaintiffs' Steering Committee with any confidential information or legal advice found in the attachments redacted.

CONCLUSION

The Court agrees, in large part, with the conclusions of the Special Master in his Eighth Report and Recommendation. The majority of the documents reviewed by the Court are not protected by attorney-client privilege or the work product doctrine. An appropriate Order follows.